File Date:	
Case No:	
ATTACHMENT #	
EXHIBIT	
TAB (DESCRIPTION)	

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APPEALING DENIED OR UNDERPAID CLAIMS

Hospitals and physicians may encounter denied, pended or underpaid claims for numerous reasons. Claims are usually pended or denied for five principal reasons:

- Administrative errors made by claims processors;
- Clerical errors made on the claim forms:
- A determination by the carrier or payer that the procedure/test is not medically necessary;
- Patient not responding to payer's request for info (i.e., verification of third party payer);
- Procedure considered "investigational" by payor.

Appealing Denied Claims

If the claim is denied, we recommend careful review of the Explanation of Benefits (EOB) for an explanation or reason for the denial. If the EOB does not clearly explain the reason, you should immediately contact your Medicare contractor, or non-Medicare payer, and request an explanation of the denied claim. In those cases where a clerical error was made on the claim form, you should simply confirm the appropriate codes to use and resubmit a corrected claim form.

In other cases, payers may deny claims based on their determination of a lack of medical necessity. Please be sure to address the issue of medical necessity immediately, and by itself. It is imperative that the payor agree that medical intervention is necessary. If this is the sole objection, you should get an approval. Once medical necessity has been established, you may proceed to address any other contingencies identified by the payor, such as the determination that the technology is considered investigational. In these cases, you should contact the Medicare contractor or non-Medicare payer and offer to provide additional information about EVLT®. You should ask the claims processor to specify what additional materials are required to reverse the original coverage determination.

If the insurance company continues to stand by their denial, you should begin the appeal process. All payers have an appeal process and you should ask the payer to forward you a written explanation of their process. You should also ask them to provide a written copy of the clinical criteria used in making this determination (the carrier is required to provide this at no cost to patients or providers). Your appeal letter should include a statement, a direct quote from the denial, as to why the EVLT® procedure was denied and why you are appealing it. When possible, include patient photos and test results, EVLT® articles and published data with your letter. A sample appeal letter with summary data is included in this section.

Many physicians have met/spoken with carrier medical directors. These collegial discussions have provided an opportunity for providers to educate payors, and have frequently resulted in a positive coverage decision. Diomed, Inc. has prepared presentation materials for use by physicians when meeting with carrier medical directors. Please contact your sales consultant or the Diomed, Inc. Director for Reimbursement at 623-322-0803 for assistance in this matter.

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Letter of Appeal	
TO BE PLACED	ON MD LETTERHEAD
Carrier Name: Carrier Address: Date:	Reference ID: Patient Name: Patient's DOB: Subscriber's Name: Insurance: Dates of Service:
Your stated reason for denial was: "The procedure is (ex	ovenous laser treatment (EVLT®) for my patient (<u>name</u>). <u>xample considered investigational or experimental</u>). The clinical viewed the data you sent and would like to address several issues.

ADDRESS ISSUES

Summary

Endovenous Laser Treatment (EVLT®) received 510K clearance from the United States Food and Drug Administration (FDA) for its laser and procedure kit for "Use in endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux", on January 22,2002. EVLT® received 510K clearance from the FDA for The Diomed D15 plus and D30 plus and EVLT® Kits on December 1, 2004 for treatment of incompetence and reflux of superficial veins in the lower extremity. Delta Laser System received 510K clearance August 18, 2005 for the following indications: General Surgery, Ophthalmology/Oculoplastic, Urology, Gastroenterology, Gynecology, Otorhinolaryngology, Pulmonary/Thoracic, Dermatology/Plastic Surgery, Neurosurgery (coagulation only), Orthopedic, Treatment of varicose veins and varicosities with superficial reflux of the Greater Saphenous Vein, Treatment of incompetent refluxing veins in the superficial venous system in the lower limb."

There have been over 200,000 limbs, worldwide, successfully treated with EVLT®. An estimated 110,000 have been performed using the Diomed laser.

There are 220 varicose vein operations/100,000 population. The basic tenet of surgery is to eliminate the incompetent venous segment at the highest point of reflux. This can be accomplished surgically via ligation and stripping or endovenously via luminal contraction and occlusion.

Comparison of results between surgical intervention and EVLT® can be made by a review of results reported in the literature. The majority of studies related to ligation and stripping of the greater saphenous vein report only one year follow up. (2) The recurrence rate documented in the literature, following vein stripping can range from 20% to 65%((12,13,17)), first seen at 3 months on duplex ultrasound. An estimated 20% of varicose vein surgeries are performed for recurrent varicosities. (61) Complications of surgery include: paresthesia along saphenous vein 25% at 2 weeks dropping to 7.7% at six months (56), wound infection — especially groin, large hematoma; incidence of deep vein thrombophlebitis (DVT) from 0.3% to 1.1% (56) dysthesia (injury to the saphenous and sural nerves), cutaneous hyperpigmentation(1) and a risk of minor complications 17% (34).

EVLT® is an alternative treatment to surgical vein ligation and stripping. Its use has been documented in six peer review articles (bibliography attached) representing 759 saphenous veins, followed for one to thirty-six months, by three different authors. All demonstrated an initial success rate (success defined as complete occlusion of the saphenous vein demonstrated by Doppler ultrasound at the end of the procedure) of 90 –100%, and a recurrence rate of less than 10%. All recurrences

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occurred within the first nine months, the majority within the first three months. Approximately four to seven days after surgery, a palpable induration/tightness has been observed in the area of anesthetic infiltration. This resolves within three to ten days. It is only seen in patients with successful outcomes (total occlusion) and it is speculated that this symptom is related to vein wall thickening and contraction of the treated vein.

Complications included: slight to moderate pain, mild to moderate ecchymosis and one transient paresthesia, all resolved within two weeks. One author (57) observed superficial thrombophlebitis in nine patients (8.7%). All resolved within two weeks. He identified these patients as high risk for revascularization associated with anticoagulant therapy, platelet inhibiting medication and high body mass index (MBI). The rate of recanalization was not statistically significantly higher. However, if the high risk patients were removed from the study, recurrence rates resembled those of other authors (<7%). Otherwise, there was **no** evidence of hematoma, infection, burns, paresthesia, cellulitis, deep vein thrombophlebitis (DVT) or pulmonary emboli (PE).

Seven abstracts were presented at the American College of Phlebology Meeting in August 2002 (two have gone on to publication and have been omitted from the following results) representing a population of 942 limbs. Follow-up ranged from 1–48 months. They demonstrated an initial success rate of 96.8-100%, with a recurrence rate of less than 7%. No complications were cited.

One additional abstract was presented at the International Symposium on Endovascular Therapy in January 2003, and two more at the Society of Interventional Radiology Meeting on March 29,2003, representing a population of 335 limbs, followed from 12 –24 months. They demonstrated a minimum of 98% initial success, with a recurrence rate of 6% or less. Complications included mild ecchymosis. There were no burns, DVT or paresthesia. All recurrences occurred within the first nine months, the majority within three months.

The same palpable induration/tightness occurred in the area of anesthetic infiltration. Again, this resolved within three to ten days and was thought to represent vein wall thickening and contraction of the treated vein.

A review of six clinical case studies (case series design studies produce high quality information with low risk of bias. Controlled conditions are not necessary because varicose veins do not heal spontaneously and EVLT® can be performed in isolation from other treatment), representing 205 limbs, followed from three to eighteen months demonstrated initial success rates of 100%. Complications included: I seroma at the access site (resolved), one temporary paresthesia (resolved) and one mild hyperpigmentation in skin type III/IV (resolved).

In a total population of 2,241 limbs with an overall average follow up of 13.8 months, EVLT® has demonstrated an overall:

- Complication rate of 0.54%
 - 9 superficial thrombophlebitis in high risk patients (resolved).
 - I seroma
 - I hyperpigmentation in skin type III/IV
 - I transient paresthesia
- Initial success rate 98.9%
- Recurrence rate: 3.3%

Three of the seven studies were prospective, non-randomized consecutive studies. Patients who chose EVLT® over surgery stated they were pleased (satisfied) with their decision. All patients who were asked stated they would recommend the procedure to a friend.

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EVLT® has consistently demonstrated superior results when compared to vein ligation and stripping:

	Surgery	EVLT*
Recurrence	20% - 80%	<10%
DVT	0.3% - 1.1%	0
Comp. Rate	17%	.54%
Paresthesia	25% @ 2 weeks; 7.7% @ 6 months	0.04% resolved in 6 weeks
Sup. Thrombophlebitis	0	0 - 0.40%

Five year outcomes for EVLT® have now been published. Results demonstrate 98% closure rate at five years compared to a recurrence rate after surgical stripping of the GSV of 73% at five years and 87% following radiofrequency ablation.

Thirty-three physicians converted from radiofrequency ablation to endovenous laser treatment (EVLT®) in 2006.

EVLT® can be performed in the physician's office, with local anesthesia. This avoids the risks of general anesthesia, surgical complications (scarring, paresthesia, bleeding, infection), the costs of inpatient hospitalization and prolonged recovery.

Productivity (societal) costs can be measured by lost workdays. Patients who choose EVLT® average 0-1 lost workdays. Patients who choose ligation and stripping average 4 days – 6 weeks and longer depending on physical job functions. Based on the United States Department of Labor, Bureau of Labor Statistics, the average total hourly compensation paid by employers per employee for civilian workers, for the fourth quarter 2003 was \$24.59. The societal cost of one missed day of work for an EVLT® patient is \$196.72. Based on 13 lost workdays (mean) following surgical ligation and stripping, the societal cost is \$2,557.36.

EVLT® has received professional recognition from the American Society for Laser Medicine and Surgery in an abstract by Dr. Luigi Mazzi stating: "Every patient who is a good candidate for surgical stripping is a good candidate for this technique, too." The procedure was also supported in an abstract by Dr. Luis Navarro and Dr. Carlos Bone' Salat at the American College of Phlebology 16th Annual Conference in November 2002. They stated: "At three years, the safety and low recanalization rates ... are superior to the safety and recurrence of ligation and stripping, making it an effective alternative or possibly the current primary treatment choice." The Society for Interventional Radiology in its valuation of literature concluded: "Endovenous ablation is an effective treatment for venous reflux and varicose veins ... these results are comparable or superior to those reported for the other options available for treatment of GSV reflux, including surgery or ultrasound-guided sclerotherapy."

The BlueCross-BlueShield Association has recommended that EVLT® be accepted for coverage by BlueCross-BlueShield payor organizations and has provided them with a sample policy stating: "...laser ablation of the greater saphenous vein, as an alternative to saphenous vein ligation and stripping ... may be considered medically necessary as a treatment of varicose veins." Additionally, EVLT® has received written coverage policies from Medicare and non-Medicare carriers (attached).

The Common Procedural Terminology Code book for 2005 first published the code for EVLT®:

36478:

Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, Laser; first vein treated

36497:

Second and subsequent veins treated in a single extremity, each through Separate access sites (list separately in addition to code for primary procedure)

Enclosures: Bibliography Policy list

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Articles:

- 1. Black, Carl MD, et.al., "Failure Rates of Endovenous Radiofrequency Ablation Compared Endovenous Laser Ablation", Journal of Vascular and Interventional Radiology, February, 2005, Vol. 16, No. 2, Part 2
- 2. Mekako, Anthony MD, et. al., "A Nonrandomized Controlled Trial of Endovenous Laser Therapy and Surgery in the Treatment of Varicose Veins", Annals of Vascular Surgery, 2006, DOI: 10.1007/s10016-006-9095-y
- 3. Min. R.J., MD: "Endovenous Laser Ablation of Varicose Veins", Journal of Cardiovascular Surgery, 2005; 46: 000-00, P

Appealing Underpaid Claims

If you feel your claim has been underpaid, contact the claims office identified on the patient's EOB, and request a review of your claim. Claims may be underpaid for various reasons including:

- Low contractual agreement;
- Incorrect coding of the actual procedure(s) performed;
- Lack or misuse of appropriate modifier;
- Lack of supporting documentation.

Each payer has their own review process, but in most cases, you will be asked to submit your request in writing. Once you determine what the process is, inquire where the request should be sent and to whom it should be directed.

Additional supporting documentation related to denied or underpaid claims, such as journal articles, are available from Diomed, Inc. upon request. These materials can be included with resubmitted claims in support of the appeal. We encourage providers to appeal all denials and underpaid claims., and are available to help with those appeals.

For additional assistance with denied or underpaid claims, please contact the Director of Reimbursement at 623-322-0803.

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CODING AND CLAIMS SUBMISSION

Coding is the language used by carriers to identify and respond to claims. Codes billed from providers must match (speak to) codes within the carrier system.

Coding

Codes serve to track utilization and establish reimbursement rates for facility and professional services. Existing codes 'fit the system'. Electronic data can be processed in a timely and uneventful fashion. Coding identifies a patient's diagnoses and treatments and any products used in the course of his or her care. Codes apply to hospital services (inpatient and outpatient) as well as physician's services. Hospital providers should report hospital-related services for the EVLT® procedure using the UB-92 (also known as the HCFA/CMS 1450) claim form. Physicians obtain reimbursement for their professional services using a different claim form than hospitals. Physicians bill for their services using the HCFA/CMS 1500 claim form.

This chapter provides information on possible coding options for hospital and physician services and coding guidelines. Sample billing claim forms are also provided for your reference.

Note: The coding options presented in this guide are not all-inclusive and are not intended to represent all coding options. Coding of principal diagnosis and procedure coding, as well as additional diagnoses and procedure coding, is dependent on the documentation in the patient's medical record. CPT codes are established and maintained by the American Medical Association. The AMA specifically states: "Do not select a CPT code that merely approximates the service provided. If no such procedure or service exists, then report the service using the appropriate unlisted procedure or service code." (Source: CPT® 2002, Instruction for Use of CPT.)

Several coding systems apply to the EVLT® procedure. The following table provides examples of each of these coding systems.

CODING SYSTEM	USED TO DESCRIBE	USED BY	EXAMPLE	DESCRIPTION					
ICD-9-CM Diagnosis	The patient's primary, secondary, etc. diagnosis that prompted treatment	Hospitals & Physicians	454.1	Varicose veins of lower extremities, with inflammation					
ICD-9-CM Procedure	What was done	Hospitals	38.80	Other surgical occlusion of vessels, unspecified					
Revenue Code	Hospital accounting centers	Hospitals	272	Sterile Supplies					
CPT* Procedure Code	Physician's professional services	Physicians	36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser 1st vein treated					
			36479	2 nd and subsequent veins treated in a single extremity, each through separate access sites (list separate- ly in addition to code for primary procedure)					

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Claims Submission

Services and their corresponding charges are reported on approved claim forms. Claim forms are relatively universal, accepted by most insurance carriers. Hospitals submit their claims on a UB-92 (also known as the HCFA/CMS 1450) claim form, for inpatient and outpatient services, while physicians use the HCFA/CMS 1500. Insurance claims are usually submitted in two ways: A) paper claims that are mailed or faxed to the payer and B) electronic claims stored on computer media and transmitted via modem.

Clean Claims

Clean claims are those submitted to the insurance company containing all the necessary information for processing. Clean claims are usually paid in a timely manner. Below is a list of several common errors that cause delay in claims processing.

- Patient's ID number is incorrect;
- · Patient's full name and address does not match the insurer's records;
- Patient's information is incomplete;
- Physician's identifying information (e.g. UPIN number) is missing;
- Physician's signature is missing;
- Hospital (authorized personnel) signature is missing;
- Dates of service are incomplete or do not match with associated claim history for the patient;
- Charges omitted;
- Invalid CPT and/or ICD-9 codes used;
- Information on claim form is illegible.

Properly coded and documented claims are the key to successful reimbursement. The **sample** claim forms provided in this section are examples of how outpatient facilities and physicians may code claims for their services. Each code should reflect the provider's usual and customary charge for the corresponding procedure.

These claims are samples only, provided to help the providers and their billing agents understand how the coding systems are reflected on the claim forms.

Please Note: Federal law prohibits fraudulent statements made on insurance claim submissions, and violations can result in both civil and criminal penalties. Diomed, Inc. strongly recommends that you consult your payers for local coverage and reimbursement policies, and follow all applicable federal, state and local laws when billing for reimbursement.

Summary Of Possible Coding Options For EVLT®

Note: This coding list is not all-inclusive and is not intended to represent all coding options. Coding of additional diagnoses and procedure codes, just as for principal diagnosis and procedure coding, is dependent on the documentation in the patient's medical record. These recommendations are based upon existent payor coverage policies for EVLT®. Final decision is at the discretion of the provider.

DESCRIPTION
Varicose veins of lower extremities, with ulcer
Varicose veins of lower extremities, with inflammation
Varicose veins of lower extremities, with ulcer and inflammation
Hemorrhage, unspecified
Pain in soft tissues of limb
Disturbance of skin sensation

Note: Medicare recognizes 4 ICD-9 codes for EVLT®. They are:

- 454.1: Varicose veins, inflamed or infected
- 454.1: Varicose veins, stasis dermatitis
- 454.1: Varicose veins, lower, ulcer
- 454.8: Varicose veins with pain, swelling
- 454.8: Varicose veins with other complications NEC
- 454.2: Varicose veins with ulcer inflamed or infected
- 454.0: Varicose ulcer (lower extremity, any part)

454.0: Varicose ulcer (lower e	extremity, any part)
ICD-9-CM ¹ PROCEDURE CODES	DESCRIPTION
38.80	Other surgical occlusion of vessels, unspecified
REVENUE CODES	DESCRIPTION
272	Sterile Supply
CPT ² PROCEDURE CODES	DESCRIPTION
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring , percutaneous, laser, I st vein treated
36479	2 nd and subsequent veins treated in a single extremity, each through separate access sites (list separately in addition to code for primary procedure)
HCPC Codes	DESCRIPTOR
Modifier ²	DESCRIPTION
Note: Modifiers should be used in a the date of service for further inform	ccordance with appropriate procedures. We recommend you review the CPT® book reflective of mation and instruction.
-PC (aka -26)	*Professional Component (Applicable only to radiological supervision & interpretation)
-TC	*Technical Component (Applicable only to radiological supervision & interpretation)
-51	Multiple Procedures

²⁰⁰² ICD-9-CM Expert for Hospitals Volumes 1, 2, and 3; International Classification of Diseases, 9th Revision, Clinical Modification; Sixth Edition; Medicode; Ingenix Companies. Current Procedural Terminology, Professional Edition (CPT*) ©Copyright 1995-2006 American Medical Association.

Possible Coding For Outpatient Hospital Services

The EVLT® procedure may be performed in various outpatient settings: outpatient hospital, Ambulatory Surgery Center, Surgicenter, and the physician's office. Most payers, including Medicare, have specific site-of-service guidelines regarding where a procedure/test may be performed. In some cases, a payer may require the EVLT® procedure to be performed in a specific facility setting. Reimbursement varies by location of service. For example, Medicare payment in the Hospital Outpatient Department (HOPD) differs from services provided in the Ambulatory Surgical Center (ASC). To obtain best/most accurate reimbursement for the EVLT® procedure, Diomed, Inc. recommends verifying payer site-of-service requirements and reimbursement specifics prior to scheduling the procedure.

Outpatient Hospital

Outpatient hospital services provided for the EVLT® procedure should be reported on the UB-92 (also known as the HCFA/CMS I450) claim form. The APC category for EVLT® is 0092. Payment based on Medicare national unadjusted average (Federal Register, 2007):

This is a facility payment only. Physicians bill separately for their services.

CPT	DESCRIPTION	APC	REL.WT.	PAYMENT	NAT'L UNADJ. CO-PAY	MIN. Co-PAY
36478	Endovenous ablation therapy of incompetent vein, inclusive of all imaging guidance and monitoring, percutaneous laser, Ist vein treated	0092	24.8809	\$1,529.38	\$309.87	\$305.88
36479	2 nd and subsequent veins treated in a single extremity, each through separate access sites (list separately in addition to code for primary pro- cedure)	0092	24.8809	\$1,529.38	\$309.87	\$305.88

UB-92 Paper Claim Form (Outpatient Hospital)

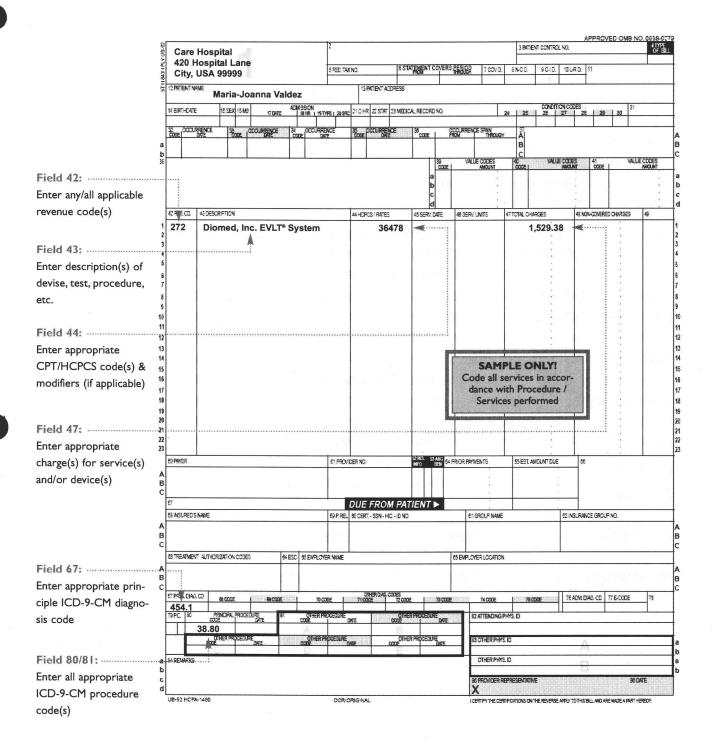
See the Sample UB-92 Paper Claim Form on the following page.

CLAIM FORM FIELD	CODE (EXAMPLES ONLY)	Guidelines
Field 42 (Revenue code)	Revenue codes will vary based on the services performed. An appropriate code might be:	Enter applicable revenue code(s) in field 42.
Field 43 (Revenue description)	272 Sterile Supply	Enter description of applicable revenue code(s) in field 43.
Field 44 (CPT*/HCPC)	CPT®/HCPC code(s) will vary based on the services(s) rendered. An appropriate code might be: 36478 Endovenous ablation therapy of incompetent vein, inclusive of all imaging guidance and monitoring, percutaneous laser, Ist vein treated 2nd and subsequent veins treated in a single extremity, each through separate access sites (list separately in addition to code for primary procedure	Enter appropriate CPT®/HCPC codes and modifiers, if applicable, in this field. Please note that these codes are required for hospital outpatient billing.
Field 67 (Principal diagnosis)	ICD-9-CM diagnosis code will vary by patient's condition and documentation. An appropriate code might be: 454.1 Varicose veins of lower extremities, with inflammation	Report appropriate diagnosis code in this field. For a more complete list of coding options, see the "Summary of Possible Coding Options for EVLT®" section of this guide, or consult your ICD-9-CM manual for a comprehensive list of coding options.
Fields 80/81 (Procedure codes)	An appropriate code for the procedure might be: 38.80 Other surgical occlusion of vessels, unspecified	Enter applicable ICD-9 procedure codes for all procedure(s) performed. For a more complete list of coding options, see the "Summary of Possible Coding Options for EVLT®" section of this guide, or consult your ICD-9-CM manual for a comprehensive list of coding options.

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Coding Source for ICD-9-CM: 2002 ICD-9-CM Expert for Hospitals Volumes 1, 2, and 3; International Classification of Diseases, 9th Revision, Clinical Modification; Sixth Edition; Medicode; Ingenix Companies.

Sample UB-92 Paper Claim Form (Outpatient Hospital)



Possible Coding For Physician Services

Physicians file claims for services provided using the HCFA/CMS 1500 paper claim form.

The following list is not all-inclusive and is not intended to represent all coding options. Coding should be specific to the procedure(s) performed and should follow established coding conventions. Any reported service or procedure should be adequately documented in the medical record. For a more complete list of coding options, see the "Summary of Possible Coding Options for EVLT®" section of this guide, or consult your AMA CPT® Manual.

HCFA/CMS 1500 Paper Claim Form (Physician)

See the Sample HCFA/CMS 1500 Paper Claim Form on the following page.

CLAIM FORM FIELD		CODE	GUIDELINES/ COMMENTS
Field 21 (Diagnosis) ICD-9-CM diagnosis code	patient's	CM diagnosis code(s) will vary by s condition and documentation. An riate code might be: Varicose veins of lower extremities, with inflammation	Report appropriate diagnosis code in this field. For a more complete list of coding options, see the "Summary of Possible Coding Options for EVLT®" section of this guide, or consult your ICD-9-CM manual for a comprehensive list of coding options.
Field 23 (Pre-certification num- ber)			Enter appropriate pre-certification number (if supplied)
Field 24D (CPT/HCPC - procedures, services or supplies)		CPC code(s) will vary based on the s(s) rendered. An appropriate code e:	Code all applicable procedures, services and supplies.
	35478	Endovenous ablation therapy of incompetent vein, inclusive of all imaging guidance and monitoring, percutaneous laser, I * vein treated	
	36479	2 nd and subsequent veins treated in a single extremity, each through separate access sites (list separately in addition to code for primary procedure)	

Sample HCFA/CMS 1500 Paper Claim Form (Physician)

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